CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

75-684

MICROBIOLOGY REVIEW

OFFICE OF GENERIC DRUGS, HFD-640

Microbiologists Review #1

April 3, 2001

Addendum:

ANDA: 75-684

Gratuitous Amendment Dated:
March 23, 2001 **(Received March 26, 2001)**

Subject of this Review

Conclusions: The above ANDAs are inclusive of the following NDAs Review and found **acceptable** by P Stinavich in HFD-805. The conclusion was initialed by P. Cooney. The same data applies to the above ANDAs.

4/3/01

Andrea S. High, Ph. D.

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REVIEW FOR HFD-150
OFFICE OF NEW DRUG CHEMISTRY
MICROBIOLOGY STAFF
MICROBIOLOGIST'S REVIEW #2 OF CBE-30 SUPPLEMENT
15 February 2001

A. 1. NDA 50-731/SCS-002 BC CBE-30
APPLICANT: Bedford Laboratories
300 Northfield Road
Bedford, OH 44146

2. PRODUCT NAMES: Danorubicin HCl Injection

3. DOSAGE FORM AND ROUTE OF ADMINISTRATION:
The product is intended for intravenous administration.

4. METHODS OF STERILIZATION:
The product is filled using an

5. PHARMACOLOGICAL CATEGORY and/or PRINCIPLE INDICATION:
The product is to be used in combination with other anticancer drugs for remission induction in acute nonlymphocytic leukemia (myelogenous, monocytic, erythroid) of adults and for remission induction in acute lymphocytic leukemia of children and adults.

B. 1. DATE OF INITIAL SUBMISSION: 9 November 2000

2. DATE OF AMENDMENT: 25 January 2001 (Subject of this Review)

3. RELATED DOCUMENTS:

4. ASSIGNED FOR REVIEW: 9 February 2001

C. REMARKS: The original submission was inappropriately filed as a Changes Being Effected in 30 Days. The document should have been filed as a Prior Approval Supplement. It seeks approval of a new filling line (South Complex Facility Upgrade , designated as Filling

The submission seeks to provide an alternate filling line for product manufacture. The filling line is designated

and is a new line installed at the applicant's facility in a refurbished area. The area includes

. During the period from 17 October 2000 to 24 October 2000 Cincinnati District Investigator Frederick Lochner conducted an inspection. A copy of the inspection report is provided in the submission.

This submission is a response to deficiencies enumerated in Microbiologist's Review #1 dated 16 January 2001.

D. CONCLUSIONS: The application is recommended for approval on the basis of sterility assurance.

15 February 2001

Paul Stinavage, Ph.D.

PHC 2/16/01

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releasable.

Micro Rev. 2

2/16/01

OFFICE OF GENERIC DRUGS, HFD-640
Microbiology Review #3
January 2, 2001

A. 1. ANDA 75-684

APPLICANT Bedford Laboratories
270 Northfield Road,
Bedford, OH 44146

2. PRODUCT NAME: Famotidine Injection

3. DOSAGE FORM AND ROUTE OF ADMINISTRATION:
10 mg/mL, 50-mL Pharmacy Bulk Vial

4. METHOD(S) OF STERILIZATION:

5. PHARMACOLOGICAL CATEGORY: Inhibitor of histamine receptors.

B. 1. DATE OF INITIAL SUBMISSION: July 30, 1999

2. DATE OF AMENDMENT: December 22, 2000
Subject of this Review (Received December 26, 2000)

3. RELATED DOCUMENTS: None

4. ASSIGNED FOR REVIEW: January 2, 2001

C. REMARKS: The subject amendment provides for the response to microbiology deficiencies in the correspondence dated December 21, 2000.

D. CONCLUSIONS: The submission is **recommended** for approval on the basis of sterility assurance. Specific comments are provided in "E. Review Notes".

Nrapendra Nath 1/2/01
Nrapendra Nath, Ph. D.

1/9/01

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micro Rev. 3

1/2/01

OFFICE OF GENERIC DRUGS, HFD-640
Microbiology Review #2
December 13, 2000

A. 1. ANDA 75-684

APPLICANT Bedford Laboratories
270 Northfield Road,
Bedford, OH 44146

2. PRODUCT NAME: Famotidine Injection

3. DOSAGE FORM AND ROUTE OF ADMINISTRATION:
10 mg/mL, 50-mL Pharmacy Bulk Vial

4. METHOD(S) OF STERILIZATION:

5. PHARMACOLOGICAL CATEGORY: Inhibitor of histamine receptors.

B. 1. DATE OF INITIAL SUBMISSION: July 30, 1999

2. DATE OF AMENDMENT: November 3, 2000
Subject of this Review (Received November 6, 2000)

3. RELATED DOCUMENTS: None

4. ASSIGNED FOR REVIEW: December 13, 2000

C. REMARKS: The subject amendment provides for the response to microbiology deficiencies in the correspondence dated August 10, 2000.

D. CONCLUSIONS: The submission is **not recommended** for approval on the basis of sterility assurance. Specific comments are provided in "E. Review Notes" and "Microbiology Comments to be Provided to the Applicant" found at the end of this review. The deficiencies represent a **Fax** amendment.

Nrapendra Nath 12/13/00
Nrapendra Nath, Ph. D.

cc:

12/13/00

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Micro Rev. 2
12/13/00

Microbiology Comments to be Provided to the Applicant

ANDA: 75-684 APPLICANT: Bedford Laboratories

DRUG PRODUCT: Famotidine Injection, 10 mg/mL;
50-mL Pharmacy Bulk Vial

A. Microbiology Deficiencies:

1. Please provide a summary of the protocol, data and the conclusions of the study validating filtration process.

2. You state that the Action Limit for the Media Fills is positive in containers filled. This Action Limit is too high. Please consider lowering the Action Limit to reflect the level common in the current industry practice.

Please clearly identify your amendment to this facsimile as RESPONSE TO MICROBIOLOGY DEFICIENCIES. The RESPONSE TO MICROBIOLOGY DEFICIENCIES should also be noted in your cover page/letter.

Sincerely yours,

Mary Fanning, M.D., Ph.D.
Associate Director of Medical Affairs
Office of Generic Drugs
Center for Drug Evaluation and Research

OFFICE OF GENERIC DRUGS, HFD-640
Microbiology Review #1
August 3, 2000

A. 1. ANDA 75-684

APPLICANT Bedford Laboratories
270 Northfield Road,
Bedford, OH 44146

2. PRODUCT NAME: Famotidine Injection

3. DOSAGE FORM AND ROUTE OF ADMINISTRATION:
10 mg/mL, 50-mL Pharmacy Bulk Vial

4. METHOD(S) OF STERILIZATION:

5. PHARMACOLOGICAL CATEGORY: Inhibitor of histamine receptors.

B. 1. DATE OF INITIAL SUBMISSION: July 30, 1999
Subject of this Review (Received August 3, 1999)

2. DATE OF AMENDMENT: None

3. RELATED DOCUMENTS: None

4. ASSIGNED FOR REVIEW: August 3, 2000

C. REMARKS: The subject drug product is manufactured at Ben Venue Laboratories' manufacturing facilities in Bedford, OH in the ____. The subject drug product is sterile filtered and ; glass vials and fitted with rubber stoppers.

D. CONCLUSIONS: The submission is **not recommended** for approval on the basis of sterility assurance. Specific comments are provided in "E. Review Notes" and "Microbiology Comments to be Provided to the Applicant" found at the end of this review. The deficiencies represent a minor amendment.

Nrapendra Nath 8/3/00
Nrapendra Nath, Ph. D.

cc:

OBH 8/8/00

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micro Rev 1

8/3/00